

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of the claims in the application:

1. - 42. (Cancelled).

43. (Previously presented) A method of transdermally delivering testosterone to a male subject in need thereof, comprising the steps of:

a. providing a hydroalcoholic gel pharmaceutical composition, consisting essentially of:

- i. about 1% testosterone;
- ii. about 45% to about 90% (w/w) alcohol selected from the group consisting of ethanol (95% w/w) and isopropanol;
- iii. isostearic acid;
- iv. about 0.1% to about 5% (w/w) thickening agent; and
- v. water; and

b. administering the composition to skin of the male subject wherein upon once daily administration of the composition, the testosterone is absorbed into bloodstream of the subject such that the circulating serum concentration of testosterone is greater than about 400 ng of testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

44. (Previously presented) The method of claim 43, wherein the isostearic acid is present in an amount greater than about 0.1% weight to weight of the composition.

45. (Previously presented) The method of claim 43, wherein the isostearic acid is present in an amount of about 0.01% to about 50% weight to weight of the composition.

46. (Previously presented) The method of claim 43, wherein the composition consists essentially of:

- a. about 1% (w/w) testosterone;

- b. about 45% to about 90% (w/w) ethanol (95% w/w);
- c. about 0.1% to about 5% (w/w) isostearic acid;
- d. about 0.1% to about 5% (w/w) thickening agent; and
- e. water.

47. (Currently amended) The method of claim 43, wherein the thickening agent ~~[[is]]~~ comprises polyacrylic acid present in an amount of about 0.9% weight to weight of the composition.

48. (Previously presented) The method of claim 47, wherein the polyacrylic acid is carboxypolymethylene.

49. (Previously presented) The method of claim 46, wherein after applying the composition to the skin of the male subject, the testosterone is absorbed into the bloodstream of the subject in an amount of at least about 10 µg per day.

50. (Previously presented) The method of claim 46, wherein the serum testosterone concentration is maintained between about 400 ng of testosterone per dl serum to about 1050 ng of testosterone per dl serum.

51. (Previously presented) The method of claim 46, wherein for each about 0.1 gram per day application of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

52. (Previously presented) The method of claim 46, wherein after at least about 30 days of daily administration serum testosterone concentration in the subject is at least about 490 ng/dl to about 860 ng/dl.

53. (Previously presented) The method of claim 46, wherein after at least about 30 days of daily administration total serum androgen concentration in the subject is greater than about 372 ng/dl.

54. (New) A hydroalcoholic gel pharmaceutical composition, consisting essentially of:
- i. about 1% testosterone;
 - ii. about 45% to about 90% (w/w) alcohol selected from the group consisting of ethanol (95% w/w) and isopropanol;
 - iii. isostearic acid;
 - iv. about 0.1% to about 5% (w/w) thickening agent; and
 - v. water.
55. (New) The composition of claim 54, wherein the isostearic acid is present in an amount greater than about 0.1% weight to weight of the composition.
56. (New) The composition of claim 54, wherein the isostearic acid is present in an amount of about 0.01% to about 50% weight to weight of the composition.
57. (New) The composition of claim 54, wherein the composition consists essentially of:
- a. about 1% (w/w) testosterone;
 - b. about 45% to about 90% (w/w) ethanol (95% w/w);
 - c. about 0.1% to about 5% (w/w) isostearic acid;
 - d. about 0.1% to about 5% (w/w) thickening agent; and
 - e. water.
58. (New) The composition of claim 54, wherein the thickening agent comprises polyacrylic acid present in an amount of about 0.9% weight to weight of the composition.
59. (New) The composition of claim 58, wherein the polyacrylic acid is carboxypolymethylene.